. .TENT COOPERATION TREA . /

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer F. Baechler
made before the expiration of 19 months from the priority of Rule 32.2(b).	
2. The election X was	
in a notice effecting later election filed with the Intern	
The designated Office is hereby notified of its election mad in the demand filed with the International Preliminary 18 August 200	Examining Authority on:
Applicant KOTWAL, Girish, J. et al	
19 January 2000 (19.01.00)	19 January 1999 (19.01.99)
International application No. PCT/US00/01115 International filing date (day/month/year)	Applicant's or agent's file reference 032513-001 Priority date (day/month/year)
Date of mailing (day/month/year) 04 October 2000 (04.10.00)	in its capacity as elected Office
NOTIFICATION OF ELECTION (PCT Rule 61.2)	Assistant Commissioner for Patents United States Patent and Trademark Office Box PCT Washington, D.C.20231 ETATS-UNIS D'AMERIQUE
PCT	To:

Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

Facsimile No.: (41-22) 740.14.35

US0001115

INTERNATIONAL SEARCH REPORT

	SSIFICATION OF SUBJECT MATTER: A61K 38/00; C07K 14/00; G01N 33/53		
US CL	:435/7.2; 514/2; 530/350		
According t	o International Patent Classification (IPC) or to bo	th national classification and IPC	
	DS SEARCHED		
Minimum d	ocumentation searched (classification system follow	red by classification symbols)	
U.S. :	435/7.2; 514/2; 530/350		
Documentat	ion searched other than minimum documentation to th	ne extent that such documents are included	in the fields searched
Flores			
	ata base consulted during the international search (r IEDLINE, CAPLUS, CAOLD, BIOSIS, EMBASE		, search terms used)
C. DOC	UMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where a	ppropriate, of the relevant passages	Relevant to claim No
Y	PASINETTI, G. M. Inflaming Neurodegeneration and Alzheimer's Complement System. Neurobiology of pages 707-716, see whole reference.	Disease: The Role of the	1-18
Y	US 5,157,110 A (KOTWAL et al) 3 reference	20 October 1992, see whole	1-18
Y	US 4,609,647 A (GROWDON et al) 0 reference.	2 September 1986, see whole	1-18
Y	US 5,855,882 A (LI et al.) 05 January	y 1999, see whole reference.	1-18
Purthe	er documents are listed in the continuation of Box C	See patent family annex.	
	cial categories of cited documents:		10
'A' doci	ument defining the general state of the art which is not considered be of particular relevance	"T" later document published after the inte date and not in conflict with the appl the principle or theory underlying the	ication but cited to understand
'E* earl	er document published on or after the international filing date	*X* document of particular relevance, the considered novel or cannot be consider	claimed invention cannot be
cne	ument which may throw doubts on priority claim(s) or which is d to establish the publication date of another citation or other real reason (as specified)	when the document is taken alone 'Y' document of particular relevance, the	·
	ument referring to an oral disclosure, use, exhibition or other	considered to involve an inventive combined with one or more other such being obvious to a person skilled in the	step when the document is documents, such combination
P docu	ument published prior to the international filing date but later than priority date claimed	*& document member of the same patent	
	actual completion of the international search	Date of mailing of the international sea	rch report
28 APRIL		23 MAY 2000	•
Name and m	ailing address of the ISA/US	Authorized officer	
Box PCT	er of Patents and Trademarks	100	j l
.Washington Facsimile No	D.C. 20231	JOSEPH MURPHY	/
	(100) 000 0200	Telephone No. (703) 308-0196 (
am PC I/IS	A/210 (second sheet) (July 1998) +		



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORTIPO

MAY 2001

WALPO PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	EOD EUDTHED ACTION	See Natif	ication of Transmittal of International
032513-001	FOR FURTHER ACTION		y Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (day/n	ionth/year)	Priority date (day/month/year)
PCT/US00/01115	19 JANUARY 2000		19 JANUARY 1999
International Patent Classification (IPC) IPC(7): A61K 38/00; C07K 14/00; G	or national classification and IP 01N 33/53 and US Cl.: 435/7.	C 2; 514/2; 530	0/350
Applicant UNIVERSITY OF LOUISVILLE RES	EARCH FOUNDATION, INC.		
This international preliming Examining Authority and is	ary examination report has transmitted to the applicant	been prepa	red by this International Preliminary Article 36.
2. This REPORT consists of a	total of <u>5</u> sheets.		
been amended and are th	panied by ANNEXES, i.e., shee e basis for this report and/or she tion 607 of the Administrative	ets containin	cription, claims and/or drawings which have ag rectifications made before this Authority. ander the PCT).
These annexes consist of a to	otal of sheets.		
3. This report contains indication	as relating to the following it	ems:	
I X Basis of the repor	rt		
II Priority			
	at of report with regard to no	velty invent	ive step or industrial applicability
IV Lack of unity of		. • • • • • • • • • • • • • • • • • • •	are step of measures approaching
=		ard to novelty	y, inventive step or industrial applicability;
citations and expla	nations supporting such statem	ent	•
	: •		
VII Certain defects in the	ne international application		
VIII Certain observation	s on the international application	on	
			!
Date of submission of the demand	Date	of completion	of this report
18 AUGUST 2000	23	APRIL 2001	ı
Name and mailing address of the IPEA/U		rized officer	
Commissioner of Patents and Tradem. Box PCT		SEPH F MI	TERRY J. DEY V
Washington, D.C. 20231	"		LALANTEDAT SUSCIENTS! A

Telephone No. (703) 30 ESPECTOLOGY CENTER 1600

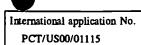
Facsimile No. (703) 305-3230

International application No.

PCT/US00/01115

I. Basis	f the report	
1 With rec	rard to the planants of the interesting	
	pard to the elements of the internation e international application as ori	
 	e description:	gmany fried
1 141	ges 1-68	
1 - '	gesNONE	, as originally filed
	o	, filed with the letter of, filed with the demand
		, med with the fetter of
نت ،	claims:	
	ges69-71	, as originally filed
	ges NONE	, as amended (together with any statement) under Article 19
	ges <u>NONE</u>	, filed with the demand
Pag	ges NONE	, filed with the letter of
X the	drawings:	
	ges1/22	, as originally filed
	ges NONE	, filed with the demand
pag	ges NONE	, filed with the letter of
X the	sequence listing part of the descri	ription:
	ges NONE	, as originally filed
	ges NONE	, filed with the demand
pag	ges NONE	, filed with the letter of
the	language of publication of the i	hed for the purposes of international search (under Rule 23.1(b)). international application (under Rule 48.3(b)).
or 5	language of the translation furnished 5.3).	d for the purposes of international preliminary examination (under Rules 55.2 and/
3. With reg	gard to any nucleotide and/or am nary examination was carried out	nino acid sequence disclosed in the international application, the international on the basis of the sequence listing:
<u> </u> -com	атес-т-стетиетацопат-аррис	eation-in-printed-form.
		application in computer readable form.
=		•
_	ished subsequently to this Author	i
		ority in computer readable form.
inter	mational application as filed has t	•
The been	statement that the information reconfurnished.	orded in computer readable form is identical to the writen sequence listing has
4. X The	amendments have resulted in the	he cancellation of:
X	the description, pagesNO	DNE
X	the claims, Nos. NO	DNE
X	the drawings, sheets/fig NO	DNE
5. This	report has been drawn as if (some	of) the amendments had not been made, since they have been considered to go
bey	ond the disclosure as filed, as indica	ated in the Supplemental Box (Rule 70.2(c)).**
* Replaceme	nt sheets which have been furnished to port as "originally filed" and are n	to the receiving Office in response to an invitation under Article 14 are referred to not annexed to this report since they do not contain amendments (Rules 70.16
**Any repla	acement sheet containing such amer	ndments must be referred to under item 1 and annexed to this report.

)



1. The o	questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to strially applicable have not been and will not be examined in respect of:
	the entire international application.
x	claims Nos. 1-18 searched in part
	because:
	the said international application, or the said claim Nos. relate to the following subject matter which does not require international preliminary examination (specify).
X Claim	the description, claims or drawings (indicate particular elements below) or said claims Nos. 1-18 are so unclear that no meaningful opinion could be formed (specify).
Claim: Becausequer	the description, claims or drawings (indicate particular elements below) or said claims Nos. 1-18 are so unclear that no meaningful opinion could be formed (specify). Solution 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing see Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the composition of the compos
Claim: Becausequer	unclear that no meaningful opinion could be formed (specify). s 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing se Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the ces per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the
Claim: Becausequer	unclear that no meaningful opinion could be formed (specify). s 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing se Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the ces per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the
Claim: Becausequer	unclear that no meaningful opinion could be formed (specify). s 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing se Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the ces per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the
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Claim: Becausequer	unclear that no meaningful opinion could be formed (specify). s 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing se Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the ces per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the
Claim: Becausequer	unclear that no meaningful opinion could be formed (specify). Solution 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing as Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the scess per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the possible with the references to the balance of the description. The claims, or said claims Nos are so inadequately supported by the description that no meaningful the claims, or said claims Nos are so inadequately supported by the description that no meaningful
Claims Because sequere extent	unclear that no meaningful opinion could be formed (specify). s 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing se Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the cess per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the possible with the references to the balance of the description. the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for said claims Nos ningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid
Claims Because sequere extent	unclear that no meaningful opinion could be formed (specify). s 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing so Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the ces per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the possible with the references to the balance of the description. the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for said claims Nos

	statement			
Inventive Step (IS) Claims 1-18 Industrial Applicability (IA) Claims 1-18 Industrial Applicability (IA) Claims 1-18 Claims NONE Industrial Applicability (IA) Claims NONE Claims NONE Claims 1-18 lack an inventive step under PCT Article 33(3) as being obvious over Pasinetti in view of U.S. Patent No. 5,157,110. Pasinetti teaches the role that the complement system plays in the chronic inflammation in Alzheimer's Disease brain. Pasinetti teaches that antiinflammatory drugs can delay the onset of AD dementia. Pasinetti does not disclose the us of a polypeptide inhibitor of the complement system. U.S. Patent No. 5,157,110 discloses a polypeptide that specifically inhibits the complement cascade. Therefore, it would have been obvious to use the complement inhibitory polypeptide disclosed in U.S. Patent No. 5,157,110 as a means of treating AD.	Novelty (N)	Claims	NONE	_ Y
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	brain. Pasinetti teaches that antiinflammator of a polypeptide inhibitor of the complement inhibits the complement cascade. Therefore disclosed in U.S. Patent No. 5,157,110 as a	ne complement s ry drugs can del t system. U.S. t, it would have t means of treati	ystem plays in the chronic inflammation in Alzheimer's Dis ay the onset of AD dementia. Pasinetti does not disclose the Patent No. 5,157,110 discloses a polypeptide that specifica been obvious to use the complement inhibitory polypeptide	ease he u
	brain. Pasinetti teaches that antiinflammator of a polypeptide inhibitor of the complement inhibits the complement cascade. Therefore disclosed in U.S. Patent No. 5,157,110 as a	ne complement s ry drugs can del t system. U.S. t, it would have t means of treati	ystem plays in the chronic inflammation in Alzheimer's Dis ay the onset of AD dementia. Pasinetti does not disclose the Patent No. 5,157,110 discloses a polypeptide that specifica been obvious to use the complement inhibitory polypeptide	ease he u
	brain. Pasinetti teaches that antiinflammator of a polypeptide inhibitor of the complement inhibits the complement cascade. Therefore disclosed in U.S. Patent No. 5,157,110 as a	ne complement s ry drugs can del t system. U.S. t, it would have t means of treati	ystem plays in the chronic inflammation in Alzheimer's Dis ay the onset of AD dementia. Pasinetti does not disclose the Patent No. 5,157,110 discloses a polypeptide that specifica been obvious to use the complement inhibitory polypeptide	ease he u
	brain. Pasinetti teaches that antiinflammator of a polypeptide inhibitor of the complement inhibits the complement cascade. Therefore disclosed in U.S. Patent No. 5,157,110 as a	ne complement s ry drugs can del t system. U.S. t, it would have t means of treati	ystem plays in the chronic inflammation in Alzheimer's Dis ay the onset of AD dementia. Pasinetti does not disclose the Patent No. 5,157,110 discloses a polypeptide that specifica been obvious to use the complement inhibitory polypeptide	ease he us
	brain. Pasinetti teaches that antiinflammator of a polypeptide inhibitor of the complement inhibits the complement cascade. Therefore disclosed in U.S. Patent No. 5,157,110 as a	ne complement s ry drugs can del t system. U.S. t, it would have t means of treati	ystem plays in the chronic inflammation in Alzheimer's Dis ay the onset of AD dementia. Pasinetti does not disclose the Patent No. 5,157,110 discloses a polypeptide that specifica been obvious to use the complement inhibitory polypeptide	ease he u
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From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: TERESA STANEK REA BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. BOX 1404 ALEXANDRIA, VA 22313-1404

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

(PCT Rule 71.1)

Date of Mailing (day/month/year)

09 WINT ZUU

Applicant's or agent's file reference

032513-001

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority Date (day/month/year)

PCT/US00/01115

19 JANUARY 2000

19 JANUARY 1999

Applicant

UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Rureau with Form PCT/IR/301)

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned. und of duare, specific a leading, lead,

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

1897, 1 4 2001

DOCKETED **C**

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

Terry J. Dey

JOSEPH F. MURPHYARALEGAL SPECIALIST

Form PCT/IPEA/416 (July 1992) *

Telephone No.



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 032513-001	FOR FURTHER ACTION	See Notifica Preliminary B	tion of Transmittal of International xamination Report (Form PCT/IPEA/416)
International application No. PCT/US00/01115	International filing date (day/m	onth/year)	Priority date (day/month/year)
International Patent Classification (IPC)	19 JANUARY 2000		19 JANUARY 1999
IPC(7): A61K 38/00; C07K 14/00; G0	01N 33/53 and US Cl.: 435/7.	2; 514/2; 530/3	150
Applicant UNIVERSITY OF LOUISVILLE RESI	EARCH FOUNDATION, INC.	·	
This international preliminal Examining Authority and is	ary examination report has transmitted to the applicant a	been prepared	d by this International Preliminary
2. This REPORT consists of a	total of <u>5</u> sheets.		
been amended and are the (see Rule 70.16 and Sect	e basis for this report and/or she tion 607 of the Administrative I	ets containing:	otion, claims and/or drawings which have rectifications made before this Authority der the PCT).
These annexes consist of a to	tal of sheets.		·
3. This report contains indication	s relating to the following ite	ms:	
I X Basis of the repor	t		
II Priority			
III X Non-establishmen	t of report with regard to nov	elty, inventive	e step or industrial applicability
IV Lack of unity of i	nvention		
V X Reasoned statemen citations and explan	t under Article 35(2) with regar nations supporting such stateme	rd to novelty, i	nventive step or industrial applicability;
	21100	• • • • • • • • • • • • • • • • • • • •	
VII Certain defects in th	ne international application		
VIII Certain observations	s on the international application	n	
Date of submission of the demand			
Date of submission of the demand	Date o	f completion of	this report
18 AUGUST 2000	.23	APRIL 2001	
Name and mailing address of the IPEA/U	- I	zed officer	mal
Commissioner of Patents and Tradema Box PCT Washington, D.C. 20231		EPH F. MUR	TERRY J. DEY V
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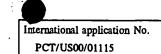
Internation

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/01115

I. E	4313	of the report	·	
1. Wi	h rega	ard to the elements of the intern	national application: *	
x		international application as		
X	1	description:	5 ,	
LX.		es1-68		
	· pag	es NONE		, as originally filed
	pag		, filed with the letter of	, filed with the demand
	F-0		, incd with the letter of	····
X	the	claims:		
	page	es69-71		, as originally filed
	page	es NONE	, as amended (together with	any statement) under Article 19
	page	es <u>NONE</u>		, filed with the demand
	page	es NONE	, filed with the letter of	
	41	, ,	* - 1 - 2**	
X		drawings: -s 1/22		
				, as originally filed
		es <u>NONE</u> NONE		, filed with the demand
	page	es <u>NONE</u>	, filed with the letter of	
x	the c	seguence listing port of the	danadakian.	
		sequence listing part of the cess	_	
		es <u>NONE</u>	-	
	Dage	NONE	, filed with the letter of	, filed with the demand
	Pag.		, filed with the letter of	
	the la	unguage of the translation furn	the international application (under Rule 48.3 nished for the purposes of international preliminar	` ' '
	or 55	.3).		
3. Wit	h rega	ard to any nucleotide and/o	r amino acid sequence disclosed in the internat	tional application, the international
pre	limina	ary examination was carried	l out on the basis of the sequence listing:	
;;	conta	uneu-in-me-international-a	ррисацоп-ип-ргинео-гогт.	
			onal application in computer readable form.	
H		shed subsequently to this A		
님				
Ш			Authority in computer readable form.	
	The s intern	statement that the subsequent ational application as filed	tly furnished written sequence listing does not has been furnished.	go beyond the disclosure in the
	The st	tatement that the information furnished.	recorded in computer readable form is identical to	o the writen sequence listing has
4. X	The a	amendments have resulted	in the cancellation of:	
	X	the description, pages	NONE	
	$\overline{\mathbf{x}}$		NONE	,
•	Ħ	the claims, Nos.		
. —	<u></u>	the drawings, sheets/fig	NONE	
5	This r	report has been drawn as if (so	ome of) the amendments had not been made, since	they have been considered to go
* D.m.1.	beyo	nd the disclosure as filed, as i	ndicated in the Supplemental Box (Rule 70.2(c)).*	*
in in	icemen is repo 70.17)	on as "onginally filed" and i	shed to the receiving Office in response to an invitation are not annexed to this report since they do not do	on under Article 14 are referred to contain amendments (Rules 70.16
	reniac	cement sheet containing such	amendments must be referred to under item 1 and	d annered to this report



III.	Non-establishment of pinion with regard t novelty, inventive step and industrial applicability
1. Th	he questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be adustrially applicable have not been and will not be examined in respect of:
	the entire international application.
Х	claims Nos. <u>1-18 searched in part</u>
	because:
	the said international application, or the said claim Nos. relate to the following subject matter which does not require international preliminary examination (specify).
	·
	·
Γ Υ	the description claims or desprings (indicate a subsular almost below) and the last
<u> </u>	the description, claims or drawings (indicate particular elements below) or said claims Nos. 1-18 are so unclear that no meaningful opinion could be formed (specify).
Cla Bec	sims 1-18 are unexamineable to the extent that they require references to specified sequences from the sequence listing. cause Applicant has not furnished a machine-readable copy of the sequence listing, no meaningful examination of the
seq	quences per se can be carried out by this Authority. However, the subject matter of the claims has been examined to the ent possible with the references to the balance of the description.
	Possesso with the restriction to the contribution
	the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed.
	no international search report has been established for said claims Nos
	
	meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid uence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
	the written form has not been furnished or does not comply with the standard.
x	the computer readable form has not been furnished or does not comply with the standard.

Form PCT/IPEA/409 (Box III) (July 1998)★

statement				
	.			
Novelty (N)	Claims Claims	NONE	•	YI
	Claims	1-10		NO
Inventive Step (IS)	Claims	NONE	•	YI
•	Claims	1-18		NO
* 1				
Industrial Applicability (IA)	Claims Claims	NONE		YI
	Ciamis	NONE		No
AT IN PARTICULAR HIMITORDE OF THE COURT	nemen system. U.S.,	Patent No. 5,157,110 discloses	a polypeptide tha	at specifically
inhibits the complement cascade. The disclosed in U.S. Patent No. 5,157,1	erefore, it would have been as a means of treating	ng AD.	zmeni inmonory p	olypeptide
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inhibits the complement cascade. The disclosed in U.S. Patent No. 5,157,1	erefore, it would have 10 as a means of treating	ng AD.		olypeptide

**Continuation of: Boxes I - VIII Sheet 10	Supplemental Box (To be used when the space in any of the preceding boxes i	s not sufficient)		
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(57) Abstract

anti-complement protein to a patient in need of such treatment in an amount sufficient to inhibit the complement cascade and thereby inhibit the production or enlargement of amyloid plaques in the brain of the patient. The present invention further provides pharmaceutical compositions comprising anti-complement protein, or derivatives thereof, and/or pharmaceutically acceptable salts thereof in a variety of unique pharmaceutical dosage forms.

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